



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 18, 2017

CareFusion
Joy Greidanus
Regulatory Affairs Manager
1500 Waukegan Road
McGaw Park, IL 60085

Re: K122422
Trade/Device Name: Pleurx Peritoneal Catheter System
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: PNG
Dated: August 8, 2012
Received: August 9, 2012

Dear Joy Greidanus:

This letter corrects our substantially equivalent letter of October 24, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K12 2422



1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.7404
FAX: 847.473.7790

510(k) Number (if known):

K122422
~~Unknown at this time~~

Device Name:

Pleurx Peritoneal Catheter System

Indications For Use:

The Pleurx Peritoneal Catheter System is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, for the palliation of symptoms related to recurrent malignant ascites and for peritoneal placement only.

The Pleurx Drainage Bottle Kits and Drainage Line Set are indicated for use either with the Pleurx Peritoneal Catheter or Pleurx Pleural Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.

The Pleurx Drainage Bag Kit is indicated for use only with the Pleurx Peritoneal Catheter for intermittent drainage.

The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.

The Pleurx Catheter Access Kit is intended to provide access to the Pleurx Catheter for aspiration and catheter maintenance.

The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the peritoneal space.

The Valved Peelable Introducers are intended for use in the percutaneous insertion of a catheter into the peritoneal space.

Prescription Use X (Per 21 CFR 801 Subpart D)
And/Or Over-The Counter Use _____ (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K122422



OCT 24 2012

510(k) SUMMARY K122422

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion
Address	1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA
Phone number	(847) 473-7404
Fax number	(847) 473-7790
Establishment Registration Number	1423507
Name of contact person	Joy Greidanus
Date prepared	October 10, 2012
NAME OF DEVICE	
Trade or proprietary name	Pleurx Peritoneal Catheter System
Common or usual name	Catheter, peritoneal, long-term, indwelling
Classification name	Peritoneal Dialysis Systems and Accessories
Classification panel	Gastroenterology/Urology
Regulation	Class II per 21CFR §876.5630, Procode PNG
Product Code(s)	Multiple
Legally marketed device(s) to which equivalence is claimed	CareFusion Pleurx Catheter Systems: K113854 Bard Aspira Pleural Drainage System: K110396 Martech (MEDCOMP) Valved Tearaway Introducer: K090394 Greatbatch (MedAmicus) Incorporated FlowGuard Peelable Introducer: K040150
Reason for 510(k) submission	Expanding the indications for use and adding accessories.
Device description	The Pleurx Peritoneal Catheter System provides patients with a convenient method to relieve malignant ascites symptoms at home. The primary components of the Pleurx Catheter System are the Pleurx Peritoneal Catheter and the Pleurx Drainage Kits.



Intended use of the device	<p>The Pleurx Peritoneal Catheter System is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, for the palliation of symptoms related to recurrent malignant ascites and for peritoneal placement only.</p> <p>The Pleurx Drainage Bottle Kits and Drainage Line Set are indicated for use either with the Pleurx Peritoneal Catheter or Pleurx Pleural Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.</p> <p>The Pleurx Drainage Bag Kit is indicated for use only with the Pleurx Peritoneal Catheter for intermittent drainage.</p> <p>The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.</p> <p>The Pleurx Catheter Access Kit is intended to provide access to the Pleurx Catheter for aspiration and catheter maintenance.</p> <p>The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the peritoneal space.</p> <p>The Valved Peelable Introducers are intended for use in the percutaneous insertion of a catheter into the peritoneal space.</p>
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SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristic	New Device	Predicates: CareFusion Pleurx Catheter System: K113854 Bard Aspira Pleural Catheter System K110396 Martech (MEDCOMP) Valved Tearaway Introducer: K090394 Greatbatch (MedAmicus) Incorporated FlowGuard Peelable Introducer: K040150
Catheter Description	Internal: fenestrations, radiopaque markings & cuff External: valve	Same
Method	Percutaneously tunneled - indwelling	Same
Means of Drainage	Wall suction, water seal drainage system, portable suction, vacuum bottles or other appropriate method	Same
Valved Peelable Introducers	Peelable sheath, dilator, hub, valve	Same
Access Kit	Provides access for sample aspirations and catheter maintenance	Same
Insertion Stylet	Reduces fluid loss, provides stiffening	Same



PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
Bench-level testing was carried out on the Pleurx Catheter System to demonstrate substantial equivalence. The performance testing requirements were determined by the predicate devices and further defined by the standards listed below. The testing conducted includes tensile strength, leakage, bond strength, deformation, security of connections, biocompatibility, aging, sterilization and residuals.	
Characteristic	Standard/Test/FDA Guidance
Biocompatibility	ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing
Residuals	ISO 10993-7:2008 Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
Performance	EN 1617:1997 Sterile Drainage Catheters and Accessory Devices for Single Use
Performance	EN 1618:1997 Catheters Other Than Intravascular Catheters – Test Methods for Common Properties
Performance	ISO 11070 Sterile, Single-use Intravascular Catheters
Performance	ANSI/AAMI/ISO 11607-1,2:2006 Packaging for Terminally Sterilized Medical Devices
Performance	ASTM F1980-07 Accelerated Aging of Sterile Barrier Systems
Performance	ISO 11138-1,2:2006 Sterilization of healthcare products - Biological Indicators
Performance	ISO 11737-1,2:2006 Sterilization of Medical Devices – Microbiological Methods Part 1 & 2
Performance	ISO 11135:2007 Medical Device, Validation and Routine Control of Ethylene Oxide Sterilization
Performance	AAMI TIR28:2009 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
N/A – No clinical tests were conducted for this submission	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
The results of the non-clinical tests show that the CareFusion Pleurx Peritoneal Catheter System meets or exceed all performance requirements, and are substantially equivalent to the predicate devices.	